

REMARKS

Reconsideration of this application in view of the above amendments and following remarks is requested. After entry of this reply, claims 22-27, 29-35 and 66-105 are pending in the application. In this Response and Amendment, claims 91 and 92 are amended, claims 102-105 are added.

Claim Objections

The Examiner objects to claims 22, 35, and 88 for the claim limitation “separate and independent distal end tubes.” The methods claimed in claims 22, 35, and 88 produce multilumen catheters that have releasably attached first and second end tubes. The releasably attached end tubes provide a medical practitioner the option to vary the separation distance between the first and second end tubes. Portions of the first and second end tubes may be separate and independent of each other if the medical practitioner choose to part the releasably attached first and second end tubes. Applicants respectfully submit that no correction is needed for the “separate and independent distal end tubes” limitation.

Claim Rejections – 35 USC § 112

The Examiner rejects claims 89, 91, and 92 under 35 USC § 112, first paragraph, as failing to comply with the written description requirement. Specifically, Examiner rejects claim 89 for lack of written description support for the claimed splitting distance, claim 91 for lack of written description support for the claimed length of the shorter first distal end tube, and claim 92 for lack of written description support for the claimed length difference between first distal end tube and the second distal end tube. The applicants respectfully submit that claims 89, 91, and 92 are adequately supported by written description in the originally filed specification.

The present patent application is a continuation-in-part of U.S. Patent Application No. 09/585, 149, which was issued as U.S. Patent No. 6,719,749 (the '749 patent). The present application incorporates by reference the entire disclosure of the '749 patent. *Para. [0001] of the present application.* The information incorporated by reference is as much a part of the application as filed as if the text was repeated in the application, and should be treated as part of the text of the application as filed. *MPEP § 2163.07(b).*

The '749 patent teaches that the unitary catheter tube is "split a distance of from about 4 cm to about 6 cm, and most preferably about 9 cm extending to the distal end 64 of the unitary tube." *'749 patent, Col. 11, lines 15-17.* This original disclosure provides ample support for the splitting distance of about 4 cm to about 9 cm of claim 89.

The '749 patent also teaches that the distal end tubes may be of different lengths, and their ends are proximally and longitudinally spaced from each other by a sufficient distance, which substantially prevents recirculation of the purified blood and blood to be purified. The distance is preferably from about 3 to about 4 centimeters (cm). *.' '749 patent, Col. 14, lines 6-13.* Applicant amended claim 92 to read "the first distal end tube is between about 3[[2]] cm to 4 cm shorter than the second distal end tube" to more closely match the written description. Given the preferred splitting distance of about 9 cm and the difference in length of the shorter first end tube and the longer second end tube is about 3 to about 4 cm, one ordinary skilled in the art would readily deduce that the length of the first end tube can about 5 to about 6 cm, i.e., subtracting the preferred splitting distance (9 cm) with the length difference between the first and second end tubes (3-4 cm). Therefore, there is ample written description support for the

amended claim 91, wherein “the shorter, first distal end tube is between about 5[[4]] cm to 6 cm in length.”

In view of the original disclosure of the present application, which incorporates by reference the ‘749 patent, and the claim amendments, Applicants respectfully request the examiner withdraw the claim rejections of claims 89, 91, and 92 based on 35 USC § 112, first paragraph.

The Examiner also rejects claims 89, 91, and 92 under 35 USC § 112, second paragraph, as being indefinite for failing to particularly point out and distinctive claim the subject matter which applicant regards as the invention. Examiner’s indefinite rejection is based on the same lack of written support as discussed in the rejections of the same claims 89, 91, and 92 based on 35 USC § 112, first paragraph..

In view of the above, claim 89 and claims 91 and 92 as amended are adequately supported in the original disclosure of the present application. Applicants respectfully request the examiner withdraw the claim rejections of claims 89, 91, and 92 based on 35 USC § 112, second paragraph.

Claim Rejections – 35 USC § 103

The Examiner rejects claims 22-25, 27, 29, 30, 33-35 and 66-101 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Davis, et al (WO 00/15289 A1). Applicants respectfully traverse the claim rejections under 35 USC §103(a), and submit that a prima facie case of obviousness has not been established.

With regard to independent claims 22, 35, and 88, Ash does not teach a unitary catheter tube with an outer wall having a smooth, curved and generally convex surface without ridges or

grooves. The multilumen catheter assembly according to the present invention assists prevention of leakage at a vessel entry site through use of the unitary catheter tube outer wall. In Ash, the catheter assembly 10 includes a splittable membrane 46 which extends longitudinally between and join the first and second catheter 26, 30. The membrane 46 allows the first and second catheters 26, 30 to be at least partially longitudinally split apart from each other without damaging the outer surfaces 34, 40 of either of the first or second catheters 26, 30. *Ash, col. 6, lines 21-24; 36-40.* In other words, the presence of the splittable membrane 46 in Ash does not, in any way, change the exterior contour of the outer wall of the joined portion of the first and second catheter tubes 26, 30. In Ash, the "cross-sectional length t_m defines the distance between the generally flat side surfaces 38, 44 of the first and second catheter tubes 26, 30. The outer wall of the catheter assembly 10 in Ash, thus, includes ridges or grooves, due to membrane 46 having a cross-sectional length t_m being a fraction of the outer diameter OD_1 of catheter assembly 10. *See Ash, col. 6, lines 54-58, and Figures 1, 1a, and 4A-4E, particularly 4A.*

With regard to independent claims 22, 35, and 88, Davis does not disclose a method of forming a splittable catheter comprising the steps of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines 12, melting and extruding the already-split tubes with stripes thereon to one another to form said preferential tear lines. Davis provides "a process for manufacturing a splittable tubular medical device that allows at least one preferential tear line to be formed in and to remain in the distal portion of the medical device even where the distal portion of the medical device is heated to form a tapered distal portion." The "preferential tear lines are provided by incorporating stripes of material having certain different characteristics from the material used to

form the major portion of the main body portion.” The splittable medical device of Davis is “formed by co-extruding the stripe material and the base material to form a tube or other configuration.” *Davis, p.4-5 (emphasis added)*. Specifically, when describing the process in detail, Davis discloses

First, a tube having the desired lumen diameter and wall thickness is extruded from a first suitable polymer ... that will comprise the major portion of the tube and a second suitable polymer ... that will comprise the striped portion of the tube. ... These stripes result in preferentially extending tear lines 12. *Davis, p.12*.

The preferential tear line of Davis is, therefore, formed in one step – co-extrusion of the tube material and the stripe material. Co-extrusion is the simultaneous extrusion of two or more different yet compatible materials through the same die. *See Dictionary.com Unabridged. Random House, Inc. <http://dictionary.reference.com/browse/coextrusion> (accessed: January 31, 2010)*. Davis therefore does not disclose a method forming a splittable catheter comprising separate steps of forming a unitary catheter tube, forming weakened portions that necessitate an initial splitting of the tubes to adhere stripes containing preferential tear lines, melting and extruding the already-split tubes with stripes thereon to one another to form said preferential tear lines. The weakened portions are formed at the same time with the main part of splittable tube via co-extrusion. Davis discloses only one extrusion step, and does not disclose further melting and extruding already-split tubes with stripes thereon to one another to form said preferential tear lines.

Davis also discloses a process for tipping the splittable tube, which contains the preferential tear line already formed by the aforementioned co-extrusion process. The tipping

process involves heating the tube on a mandrel, and in a die having an interior molding surface according to the desired shape of the distal portion of the tube. *Davis, p.12*. Davis requires the tube material and the stripe material to have similar melting and flow properties, so that the co-extruded tube can be tipped using the above heating process and retaining the preferential tear line. *Davis, p.10*. The tipping process of the Davis is carried out after the formation of the tube with the preferential tear line. It is a step for shaping the splittable tube, thus, is not a step necessary for the formation of the preferential tear line. The Davis process, therefore, does not disclose a step of releasably bonding or releasably attaching/reattaching a first end tube and a second end tube.

In view of the above, Ash and Davis, either alone or in combination, do not disclose all the elements of independent claims 22, 35, and 88. It follows that Ash and Davis, either alone or in combination, do not disclose all the elements of dependent claims 23-25, 27, 29, 30, 33, 34, 66-87, 89-101.

The Examiner further rejects claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash, et al (U.S. Patent No. 5,947,953) in view of Davis, et al (WO 00/15289 A1), and further in view of Melsky et al (U.S. Patent No. 5,704,915). Applicants respectfully traverse the claim rejections under 35 USC §103(a), and submit that a prima facie case of obviousness has not been established.

In view of the above, Ash and Davis, either alone or in combination, do not disclose all the elements of independent claim 22. It follows that Ash, Davis and Melsky, either alone or in combination, do not disclose all the elements of dependent claims 31 and 32.

Applicants respectfully request that the Examiner withdraw the rejections of claims 22-

25, 27, 29, 30, 33-35 and 66-101 under 35 USC §103(a) as unpatentable over Ash in view of Davis, and claims 31 and 32 under 35 USC §103(a) as unpatentable over Ash in view of Davis and further in view of Melsky.

Claims Added by this Response and Amendment

Claims 102-105 are added in this Response and Amendment to more completely cover certain aspects of Applicants' invention. The recitations of claims 102-105 are patentable over the prior art of record for the reasons detailed above, as the added claims include features similar to those currently and variously presented. Particularly, for newly added claim 102, Ash does not disclose forming "an outer wall comprising an outer surface having a cross-section defining a shape that is continuously convex at every point of the shape, and a single, longitudinal planar wall generally bisecting the unitary catheter tube along a longitudinal plane to form at least first and second lumens having generally equal cross-sectional areas," and "splitting a portion of the unitary catheter tube longitudinally by slicing a portion of a length of the single, longitudinal planar wall along the longitudinal plane to form a first distal end tube and a second distal end tube."

Additionally, for these reasons the added claims are fully supported throughout the specification and the drawings. Nonetheless, by way of example, and for the convenience of the Examiner, disclosure for recited features can be found in the specification at least as follows: FIGs. 2c, 2f, Para. [0056], [0063], [0064], [0115], and [0120]-[0123].

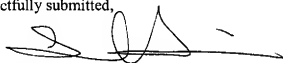
CONCLUSION

In light of the above amendments and remarks, Applicants submit that pending claims 22-27, 29-35 and 66-105 are allowable, that the application is in condition for allowance, and requests that the Examiner issue an early notice of allowance. The Examiner is invited to call the undersigned attorney to advance prosecution of this application.

The Commissioner is hereby authorized to charge any deficiency or credit any overpayment of the fees associated with this communication to Deposit Account No. 02-2555.

Date: February 1, 2020

Respectfully submitted,

A handwritten signature in black ink, appearing to be 'Shawn Li', written over a horizontal line.

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